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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,888	02/04/2004	James M. Brugger	53951-118	5367

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PROSKAUER ROSE LLP  
PATENT DEPARTMENT  
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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/772,888

Applicant(s)

BRUGGER ET AL.

Examiner

John Kim

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/4/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). There are two claims that are numbered claim 8 and claim 9 is missing.

Misnumbered 2<sup>nd</sup> claim 8 has been renumbered claim 9. For the examination purposes, 2<sup>nd</sup> claim 8 is considered claim 9. Appropriate correction of the numbering of claims is needed in response to this office action.

2. The disclosure is objected to because of the following informalities: Under continuity data of the application, US Serial No. 09/905,171 filed July 13, 2001 needs to be updated as “abandoned”.

Appropriate correction is required.

3. Claims 9-13 are objected to because of the following informalities: Claims 9-13 depend on claim 7 which recites “A system” rather than “An apparatus in preamble. It appears claims 9-13 were intended to be dependent upon claim 8 instead of claim 7. Appropriate correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Recitations of “the fluid source” on line 8 of claim 8 and “the fluid container” on line 2 of claim 11 lack a positive antecedent basis.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,024,657 (hereinafter referred to as Needham et al.). Needham et al teach a fluid processing system comprising a fluid source (310) connected to a tubular connector (308) and a fluid circuit comprising an inlet (76a”) and an outlet (76b”) and the tubular connector (308) comprising a spiked first fluid passage (342) at a higher gravity height than a spiked second fluid passage (340) and coupled to the outlet (326) to an fluid outlet (76b”) and the spiked second fluid passage (340) connected to the inlet (324) to an fluid inlet (76a”) wherein the fluid circuit includes a filter (84) (see figures 1, 18-19; col. 9, line 1-31; col. 23, line 60 – col. 25, line 65). Recitation of a loop is not given a patentable weight because structural elements and connections forming a loop are not positively claimed.

8. Claims 1-2, 7, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,439,179 (hereinafter referred to as Lueders et al.). Lueders et al teach a fluid processing system comprising a double lumen spike tubular connector (18) to penetrate diaphragm port (19) of the fluid source bag (11) wherein spike portion have inlet and outlet

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openings mutually spaced apart and separately communicating with inlet and outlet passages (29, 21) therewithin, a releasable branched tubing set (14) connected to the spike connector (18) to separate inlet and outlet fluid lines (26, 20) of a fluid circuit wherein the fluid circuit has a filter (22) as a part of peritoneal dialysis system (see figure 1; abstract; col. 1, lines 5-7; col. 3, line 46 – col. 4, line 15; col. 5, line 63 – col. 6, line 17). Recitation of a loop is not given a patentable weight because structural elements and connections forming a loop are not positively claimed.

9. Claims 1-2, 5-9, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,772,624 (hereinafter referred to as Utterberg et al '624). Utterberg et al '624 teach a fluid processing system comprising a fluid source connected to a tubular connector (160) via a saline line (168) and a fluid circuit comprising an inlet with a luer fitting (48) and an outlet with a luer fitting (70) and a tubular connector comprising a first fluid passage (184) coupled to the outlet luer fitting (70) via a corresponding luer fitting (196) and a separate second fluid passage (164) connected to the inlet luer fitting (48) via a corresponding luer fitting (176) wherein a fluid circuit is a hemodialysis system including hemodialyzer (10) between lines (56, 22) in the fluid circuit (see figures 1-2, 8A, 11; col. 1, lines 1-13; col. 3, lines 25-28; col. 7, line 19 – col. 9, line 27; col. 10, line 45 – col. 11, line 37; col. 13, line 23 – col. 14, line 18).

Recitation of a loop is not given a patentable weight because structural elements and connections forming a loop are not positively claimed.

10. Claims 1-4, 6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,649,063 (hereinafter referred to as Brugger et al.).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

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102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Brugger et al teach a fluid processing system comprising a fluid source container (800) connected to a connector assembly comprising a first fluid passage connected to an inlet of the fluid circuit via a luer connector (93) and a second fluid passage connected to an outlet of the fluid circuit via connector (21) wherein a fluid circuit comprising a hemofilter forming a fluid circuit of hemofiltration and hemodiafiltration system and fluid source container and connector assembly are pre-connected and sterilized as a disposable kit (see figures 4-6; col. 6, line 4 – col. 8, line 16). Recitation of a loop is not given a patentable weight because structural elements and connections forming a loop are not positively claimed.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3-4, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg et al ‘624 as applied to claim 2 and 7 above and further in view of US Pat. No. 5,211,849 (hereinafter referred to as Kitaevich et al.). Utterberg et al ‘624 teach that their apparatus can be used in a hemodialysis method or other desired blood treatment methods (col. 1, lines 1-13; col. 3, lines 25-28). Claims 23-24, 26, 28, 32, 34, 36, 43-44, 46 and 48 differs from the apparatus of Utterberg et al ‘624 in reciting a portion of fluid circuit being a portion of


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hemofiltration system, hemodiafiltration system or having a hemofilter. Kitaevich et al teach a multipurpose blood treatment systems and methods including hemofiltration including a hemofilter and hemodiafiltration system (see figure 1; col. 2, line 35-57). It would have been obvious to a person of ordinary skill in the art to incorporate the apparatus of Utterberg et al '624 into well-known blood treatment systems such as hemofiltration system, hemodiafiltration system or system having a hemofilter as suggested by Utterberg et al '624.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
January 9, 2006